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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,451	02/05/2002	Ronald Brown Miller	222.1101CON	8520

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,451	MILLER ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination, dated 1-30-04 is acknowledged.

Claims 1-8 and 11-25 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-30-04 has been entered.

Summary:

Instant claim 1 is directed to an oral, a solid, controlled release pharmaceutical formulation comprising an extrudate comprising an active agent and a matrix in the formulation. Claim 1 recites specific solubility of the active agents and recites specific relelase patterns of the active agent, as tested by Ph. Eur. Basket Method, wherein the extrudate is directly incorporated into a tablet or capsule. Claim 1 primarily requires two components an active agent and a matrix. Dependent claim 4 recites that the matrix comprises a mixture of hydrophobic fusible material having a melting point of greater than 40 degrees C and a hydrophilic polymeric fusible wicking agent. Claim 8 recites a solid controlled release formulation prepared by the recited process steps.

The following is a new rejection:

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 6-8, 11-16 and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/09066 (hereafter WO '066).

WO '066 discloses a controlled release composition comprising an active agent, a polymeric matrix comprising a water-soluble polymer and a surface-active agent, for a zero order relelase rate (abstract, page 13, last paragraph; page 14, lines 14-18). The surface-active agents of WO '066 include fatty acid esters and fatty acid ethers having 12 to 24 carbon atoms, which read on the instant hydrophobic fusible agents (page 7, lines 23 to page 8, line 4). WO does not state the melting point, however, instant specification also include fatty acid esters and fatty acid ethers as suitable fusible materials and accordingly, WO '066 meet the claimed requirement. WO '066 discloses polyethylene glycol as a suitable hydrophilic material and recites the molecular weight of PEG that is within the ranged disclosed in the instant specification (page 9, lines 4-17). WO '066 further discloses that the active agent will have a particle size in the range of 0.1 to 500 microns and also disclose multiparticulate forms (page 11; page 17, lines 27-35). With respect to the claimed "extrudate", WO discloses that the composition is extruded (page 18, lines 18-30; page 19, lines 1-5 & lines 12-16 & page 20, lines 8-14). With respect to the claimed water soluble substance, in particular, morphine and the release rates, WO '066 discloses morphine hydrochloride preparation in example of (page 28), where the composition comprises a matrix formed of a molten mixture of hydrophilic polymer (dextrin) and PEG monostearate was extruded. Thus, WO '066 meets the limitations of claims 6, 13, 19 and 21.

With respect to the claimed release rates (of claims 1-3 and14-17), dissolution parameters i.e., ratio of Cmax to mean plasma levels, tmax, W50 etc., and the claimed test method, it is examiner's position that because WO '066 discloses claimed polymers of the matrix and also morphine, the release rates claimed are inherent to the compositions. WO '066 further discloses that the release of the active agent is achieved for a long time i.e., 8 hours or more (table on page 32). With respect to claim 11, the limitation "the dosage form being obtainable by a process comprising:" even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." With respect to claims 8, 22 and 23, "suitable for once-a-day dosing" is an intended limitation that carries no patentable weight. Therefore, for the reasons above, WO '066 anticipates instant claims.

Claim Rejections - 35 USC § 103

2. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 89/09066 (WO '066).

WO '066 discussed above fails to teach the instant ratios of hydrophobic and hydrophilic components of matrix. However, WO '066 teaches the compositions for controlled zero order relelase rates of active agents (page 11) and also teaches the claimed morphine compounds. Further, WO '066 teaches that the combination of surface-active agents and the polymer in the

matrix enable the release of drug at a substantially constant rate. Therefore, it would have been within the scope of a skilled artisan at the time of the instant invention to optimize the amounts of surface-active agents and the soluble polymer in the formulation of WO '006 such that a homogenous matrix is obtained which provides a zero order release rate of the active agent.

The following rejection of record has been maintained:

3. Claims 1-8 and 11-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 11-22 of U.S. Patent No. 6,399,096. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant solid, oral, controlled relelase formulations are generic to all water-soluble active ingredients, including the specific drugs such as morphine, tramadol etc., of the patented claims. Besides, both sets of claims recite that the drug is dispersed in a matrix, which results in the same in vitro dissolution rates. Accordingly, the species of the patented claims anticipates the claimed genus of the instant application, and therefore, a patent to the genus would necessarily, extend the rights of the species should the genus issue as a patent after the species.

4. Claims 1-8 and 11-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,965,163. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant solid, oral, controlled relelase formulations are generic to the particulate solid

dosage forms of the patented claims because instant dependent claim recite microparticulates. Besides, both sets of claims recite the similar of matrix and also morphine as the active agent in the dependent claims. Instant claim 11 recites the product by process claim, which overlaps with the patented product by process claims. Absent any distinction in the active agent or matrix materials, the patented solid dosage form inherently possess the ability to produce the claimed release rates, as tested by the specified method of instant claims. Accordingly, the species of the patented claims anticipates the claimed genus of the instant application, and therefore, a patent to the genus would necessarily, extend the rights of the species should the genus issue as a patent after the species.

5. Claims 1-4, 8, 11, 12, 14-16 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,828,836 to Elger et al (hereafter Elger).

Elger discloses a solid, controlled release pharmaceutical formulation comprising an active agent incorporated in a controlled release matrix comprising a water-soluble polydextrose, for achieving a slow relelase of drug over extended periods of time. (Col. 1). Elger discloses that the matrix also contains at least one digestible C8-C50 substituted or unsubstituted hydrocarbon, especially a C12-C36 fatty alcohol such as polyethylene glycol and optionally contains hydroxyalkyl or carboxyalkylcellulose (col. 2, lines 11-35). The matrix polymer, polydextrose, and polyethylene glycol taught by Elger read on the instant matrix materials. Although Elger does not state the melting point as claimed, the property is inherent to the compounds because instant specification also states polyethylene glycol as the suitable hydrophobic agent having the claimed melting point. Elger also discloses tablets and capsule, as claimed. The teachings of

pellets and granules by Elger meet the claimed particulates because the instant claims do not state the particle size. With respect to the limitations regarding specific release rates, dissolution parameters i.e., ratio of Cmax to mean plasma levels, tmax, W50 etc., and the claimed test method, it is examiner's position that because Elger discloses claimed polymers of the matrix and also discloses various active agents (col. 3) that include the water soluble active agents (for and also discloses various active agents (col. 3) that include the water soluble active agents (for example theophylline in col. 8 and pyridoxine hydrochloride in col. 8, both of which are water soluble), the release rates claimed are inherent to the compositions. Elger further discloses that the release of the active agent is achieved for a long time i.e., 8 hours or more (col. 1, lines 7-12) and figure 2 shows that the release is achieved over 15 –20 hours.

Elger does not state "extrudate" or "extrudate is directly incorporated into tablet or a capsule", as required by claim 1. Further, with respect to claim 11, Elger does not teach "the dosage form being obtainable by a process comprising:" the limitation. However, the above limitations are related to the process of making the composition, and do not constitute a positive limitation. Furthermore, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elger et al (hereafter Elger).

Instant claims recite a specific ratio of hydrophobic fusible agent and the polymer.

Elger, discussed above, fails to teach exactly the same ratios as claimed, 8:1 to 16:1 and instead teaches a ratio of 1:4 to 4:1. However, the examples of solid controlled relelase compositions taught by Elger (in cols. 7 and 8), Elger teaches a higher amount of hydrophobic polyethylene glycol as compared to polydextrose. Further, Elger teaches the above matrix components for the same purpose as claimed. Accordingly, optimizing the amounts of the hydrophobic and hydrophilic agents in the compositions of Elger so as to achieve a sustained release rate of a given active agent would have been obvious for one of an ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 1-30-04 have been fully considered but they are not persuasive.

Double patenting rejection:

Applicants stated that upon indicating the allowable subject matter, the filing of terminal disclaimers will be considered. Therefore, the rejections have been maintained.

Rejection over Elger-102(b) & 103(a):

Applicants argue that instant claim 1 has been amended to state "an extrudate.....wherein extrudate is directly incorporated into a tablet or a capsule", in order to expedite the issuance of a

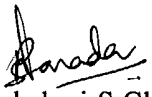
patent and that fails to teach or suggest the formulations comprising an 'extrudate". Further, applicants argue that claim 11 recites "extruding the agglomerates ...an elongate extrudate is formed into pieces", which is not taught by Elger. Applicants argue that limitations 5 and 17, rejected as being unpatentable over Elger et al, are dependent from claims 1 and 11 respectively and that because Elger fails to teach "extrudate" or "extruding", Elger fails to suggest the instant claims.

Applicants' arguments are not persuasive because as mentioned in the rejection above, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Applicants have not argued regarding the teachings of the claimed soluble material, and the hydrophobic and hydrophilic materials comprising the matrix (of Elger). Similarly, the limitations "an extrudate" and "extruding" refers to the process by which the composition is prepared. The argued limitations are part of the process steps that does not carry patentable weight. Accordingly, the rejection has been maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 9, 2004